DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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Silver Spring, MD 20993-0002

October 16, 2014

AGFA HealthCare N.V.
% Ms. Shaeann Cavanagh
Regulatory Affairs Specialist NA
10 South Academy Street
GREENVILLE SC 29601

Re: K142184
Trade/Device Name: DX-D Imaging Package
Regulation Number: 21 CFR 892.1680
Regulation Name: Stationary x-ray system
Regulatory Class: II
Product Code: MQB
Dated: August 8, 2014
Received: August 8, 2014

Dear Ms. Cavanagh:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638 2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

for

Janine M. Morris
Director
Division of Radiological Health
Office of In Vitro Diagnostics
and Radiological Health
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*

K142184

Device Name

DX-D Imaging Package

Indications for Use *(Describe)*

Agfa's DX-D Imaging Package is indicated for use in general projection radiographic applications to capture for display diagnostic quality radiographic images of human anatomy. The DX-D Imaging Package may be used wherever conventional screen-film systems may be be used.

Agfa's DX-D Imaging Package is not indicated for use in mammography.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) *(Signature)*

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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510(K) SUMMARY
Agfa's DX-D Imaging Package – DX-D40C/G Detectors

Common Name: Solid State X-Ray Imager (Flat Panel/Digital Imager)
Classification Name: Stationary X-Ray System
Regulatory Classification: 21 CFR 892.1680
Product Code: MQB
Proprietary Name: DX-D Imaging Package
Agfa HealthCare N.V.
Septestraat 27
B-2640 Mortsel
Belgium
Contact: Koen Vervoort, Prepared: August 8, 2014
Telephone: +32-34444-7368

A. LEGALLY MARKETED PREDICATE DEVICES

This is a 510(k) for Agfa's DX-D Imaging Package, a solid state, flat panel x-ray imaging device. It is substantially equivalent to systems with Agfa's DX-D Imaging Package (K121095) and Viework's ViVIX-S Wireless Panel (K122865).

B. DEVICE DESCRIPTION

Agfa's DX-D Imaging Package is a solid state flat panel x-ray system, a direct radiography (DR) system (product code MQB) intended to capture images of the human body. It is a combination of Agfa's NX workstation and one or more flat-panel detectors.

This submission is to add the DX-D40C/G Flat Panel Detector to Agfa's DX-D Imaging Package portfolio. Agfa's DX-D40C/G is currently marketed by Vieworks as the ViVIX-S Wireless Panel (K122865), which is one of predicates for this submission.

Principles of operation and technological characteristics of the new and predicate devices are the same. The new device is physically and electronically identical to both predicates, K121095 and K122865. It uses the same workstation as predicate K121095 and the same scintillator-photodetector flat panel detectors to capture and digitize the images as predicate K122865.

Laboratory data and image quality evaluations conducted with independent radiologists confirm that performance is equivalent to the predicates.

C. INTENDED USE

Agfa's DX-D Imaging Package is indicated for use in general projection radiographic applications to capture for display diagnostic quality radiographic images of human anatomy. The DX-D Imaging Package may be used wherever conventional screen-film systems may be used.

Agfa's DX-D Imaging Package is not indicated for use in mammography.

Intended use has not changed as a result of any labeling modification(s).

D. SUBSTANTIAL EQUIVALENCE SUMMARY

Agfa's DX-D Imaging Package has an Indications For Use statement identical to the predicate device (K121095) and similar to predicate device (K122865). Intended uses are the same. The devices have the same technological characteristics.

The DX-D Imaging Package indications for use is substantially equivalent to both predicate devices (K121095& K122865). The DX-D Imaging Package and both predicate devices (K121095 & K122865) include the statement that the device is not indicated for mammography. The DX-D Imaging Package and both predicate devices (K121095 & K122865) describe the imaging applications may be used utilized where screen-film systems exist. Differences in devices do not alter the intended diagnostic effect.

The new device and the both predicate devices (K121095 & K122865) are solid state imaging devices, Product Code MQB. Agfa's DX-D Imaging Package is substantially equivalent to both predicate devices (K121095 and K122865) in that it uses precisely the same technology to capture and transmit images.

Principles of operation and technological characteristics of the new and predicate devices are the same. The new device is physically and electronically identical to both predicates, K121095 and K122865. It uses the same workstation as predicate K121095 and the same scintillator-photodetector flat panel detectors to capture and digitize the images as predicate K122865.

Agfa's DX-D40C/G is currently marketed by Vieworks as the ViVIX-S Wireless Panel (K122865), which is one of the predicates for this submission.

Performance data including laboratory image quality measurements (DQE), image quality clinical evaluations, standard GenRad workflow tests, and a usability evaluation are adequate to ensure equivalence.

PRODUCT COMPARISON TABLE			
	DX-D Img Pkg (New Device)	**AGFA DX-D Imaging Package (PREDICATE-K121095)**	**Vieworks ViVIX-S (PREDICATE-K122865)**
Communications	Same as predicates	DICOM	DICOM
Flat Panel	Same as predicates	Flat Panel Detector	Flat Panel Detector
Detector Material	Same as predicates	Gadolinium Oxysulfide (GOS) or Cesium Iodide (CsI) scintillator	Gadolinium Oxysulfide (GOS) or Cesium Iodide (CsI) scintillator
Detector Sizes	Same as predicates	17x17 in. 14x17 in.	17x17 in. 14x17 in.
Active Matrix (14x17 in.)	Same as predicates	2560 x 3072	2560 x 3072
Pixel size	Same as K122865	139 µm	140 µm
Dynamic Range	Same as predicates	14 bit	14 bit
Maximum Image Acquisitions/hr.	Same as predicates	150	150
Power Supply	Same as predicates	50-60 Hz 100-240V auto ranging	50-60 Hz 100-240V auto ranging
Operator Workstation	Same as K121095	Agfa NX	Intel PRO 1000 Series
Image processing	Same as K121095	MUSICA	VXvue
Operating system	Same as predicates	Windows 7	Windows 7
Display System	Same as K121095	Separately cleared medical display (K051901)	Standard PC display or separately cleared medical display
Indications for Use	Agfa's DX-D Imaging Package is indicated for use in general projection radiographic applications to capture for display diagnostic quality radiographic images of human anatomy. The DX-D Imaging Package may be used wherever conventional screen-film systems may be be used. Agfa's DX-D Imaging Package is not indicated for use in mammography.	Agfa's DX-D Imaging Package is indicated for use in general projection radiographic applications to capture for display diagnostic quality radiographic images of human anatomy. The DX-D Imaging Package may be used wherever conventional screen-film systems may be used. Agfa's DX-D Imaging Package is not indicated for use in mammography.	The ViVIX-S Wireless is indicated for digital imaging solution designed as a general radiographic system for human anatomy. It is intended to replace film or screen based radiographic systems in all general purposes of diagnostic procedures. It is not to be used for mammography.

E. TECHNOLOGICAL CHARACTERISTICS

Agfa's DX-D Imaging Package is a solid state flat panel x-ray system, a direct radiography (DR) system (product code MQB) intended to capture images of the human body. It is a combination of Agfa's NX workstation and one or more flat-panel detectors.

Principles of operation and technological characteristics of the new and predicate devices are the same. The new device is physically and electronically identical to the predicates K121095 and K122865. It uses the same workstation as predicate K121095 and the same scintillator-photodetector flat panel detectors to capture and digitize the images as predicate K122865. There are no differences between the device and the predicates (K121095 & K122865) that impact safety and effectiveness.

The DX-D 40C/G DR Panel can be used with each modality that has not been equipped with a separate DR panel. It is a non-integrated system including the generator and tube. When using Siemens or Sedecal generators (integrated system), there is a link between the NX workstation and the generator to send exposure parameters. This link is validated by Agfa Service Technicians. However, for every installation Agfa Service Technicians perform an acceptance test to guarantee the system is working as intended without integration issues.

F. TESTING

Laboratory testing and software testing (for a moderate level of concern device) using equivalent test protocols as used for the cleared detectors were evaluated by qualified individuals employed by the sponsor to demonstrate that adequate design controls (according to 21 CFR 820.30) were in place.

Laboratory image quality measurements (DQE), image quality clinical evaluations, standard GenRad workflow tests, and a usability evaluation data has been provided.

In-hospital image quality comparisons have been conducted with qualified independent radiologists as well.

Standard GenRad workflow performance and Usability of the complete system have been validated.

Where patient images were utilized, they were first anonymized to remove all identifying patient information. No animal or clinical studies were performed in the development of the new device. No patient treatment was provided or withheld.

The product, manufacturing and development processes conform to product safety and medical imaging standards including:

G. PRODUCT STANDARDS

- ACR/NEMA PS3.1-3.20: 2011 Digital Imaging and Communications in Medicine (DICOM).
- IEC 60601-1: 2012 Medical Electrical Equipment: General Requirements for Safety and Essential Performance.
- IEC 60601-1-2: 2007 Medical Electrical Equipment - Part 1-2: General Requirements for Safety and Essential Performance - Collateral Standard: Electromagnetic Compatibility - Requirements and Tests.

QUALITY MANAGEMENT STANDARDS

- ISO 14971:2007 Application of Risk Management to Medical Devices
- ISO 13485:2003 Medical Devices - Quality Management Systems - Requirements For Regulatory purposes

H. RISK ASSESSMENT AND MANAGEMENT SUMMARY

During the final risk analysis meeting, the risk management team concluded that the medical risk is no greater than with conventional x-ray film previously released to the field.

For the DX-D40C/G (XRDi15 software) there are a total of 41 risks in the broadly acceptable region and two risks in the ALARP region. Zero risks were identified in the Not Acceptable Region. Therefore, the device is assumed to be safe, the benefits of the device are assumed to outweigh the residual risk.

There are no residual risks for the released NX software versions NX8800 (NX Ikonos) in the ALARP region after mitigation. Only two risks were identified in the Broadly Acceptable Region. Therefore, the device is assumed to be safe, the benefits of the device are assumed to outweigh the residual risk.

The term "Level of Concern" means the level of risk that the software device is determined to be if the software were to fail. The Level of Concern for the device has been determined to be moderate.

I. CONCLUSIONS

Agfa's DX-D Imaging Package has an Indications For Use statement identical to the predicate device (K121095) and similar to predicate device (K122865). Intended uses are the same. The devices have the same technological characteristics.

The DX-D Imaging Package indications for use is substantially equivalent to both predicate devices (K121095& K122865). The DX-D Imaging Package and both predicate devices (K121095 & K122865) include the statement that the device is not indicated for mammography. The DX-D Imaging Package and both predicate devices (K121095 & K122865) describe the imaging applications may be used utilized where screen-film systems exist. Differences in devices do not alter the intended diagnostic effect.

The new device and the both predicate devices (K121095 & K122865) are solid state imaging

devices, Product Code MQB. Agfa's DX-D Imaging Package is substantially equivalent to both predicate devices (K121095 and K122865) in that it uses precisely the same technology to capture and transmit images.

Principles of operation and technological characteristics of the new and predicate devices are the same. The new device is physically and electronically identical to both predicates, K121095 and K122865. It uses the same workstation as predicate K121095 and the same scintillator-photodetector flat panel detectors to capture and digitize the images as predicate K122865.

Agfa's DX-D40C/G is currently marketed by Vieworks as the ViVIX-S Wireless Panel (K122865), which is one of the predicates for this submission.

Performance data including laboratory image quality measurements (DQE), image quality clinical evaluations, standard GenRad workflow tests, and a usability evaluation are adequate to ensure equivalence.

This 510(k) has demonstrated Substantial Equivalence as defined and understood in the Federal Food Drug and Cosmetic Act and various guidance documents issued by the Center for Devices and Radiological Health.